

Management System: Quality Assurance and Oversight

Subject Area: Quality Assurance Records

Procedure: Quality Assurance Records

Issue Date and Revision Number:
04/09/15 1

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1.0 Applicability

This document provides for the control of quality assurance (QA) records. This document applies to all Environmental Management Consolidated Business Center (EMCBC) and participating Small Sites Federal or support contractor personnel performing QA activities.

2.0 Required Procedure

IDENTIFICATION AND CLASSIFICATION OF QA RECORDS	
Step 1	The EMCBC Office of Technical Support and Asset Management and participating Small Sites shall identify a QA Records Coordinator.
Step 2	The QA Records Coordinator shall ensure QA records are identified and are included in the Records Generated Table of implementing procedures. Note: See Exhibit 1 – EMCBC QA Records Identification Matrix
Step 3	The QA Records Coordinator shall provide the Records Management staff the QA records classification and retention to be documented on the Organizational/Site File Plan. Note: See Exhibit 2 – EMCBC QA Records Classification Matrix
GENERATION AND AUTHENTICATION OF QA RECORDS	
Step 4	The QA record generator shall ensure QA records are generated, completed, and authenticated per the applicable implementing procedure or document.
Step 5	The QA record generator shall ensure that QA records are legible, traceable to associated items and activities, and accurately reflect the work accomplished or information required.
SUBMITTING COMPLETED QA RECORDS	
Step 6	When a QA record, or QA record package, has been completed and authenticated the QA record generator shall submit the QA record to the QA Records Coordinator along with the completed QA Records Transmittal Form (FM-OTSAM-414E-01-F1).

RECEIPT CONTROL OF QA RECORDS	
Step 7	The QA Records Coordinator shall document receipt and inspection of the QA record on the QA Records Transmittal Form (FM-OTSAM-414E-01-F1). QA records found deficient shall be returned for correction.
CORRECTION OF QA RECORDS	
Step 8	Corrections to QA records, including documents that will become QA records, shall include the initials or signature of the personnel who generated the QA record, the QA Records Coordinator, or authorized QA personnel; who made the correction and the date the correction was made. The corrected QA record is then resubmitted to the QA Records Coordinator.
STORAGE AND MAINTENANCE OF QA RECORDS	
Step 9	The QA Records Coordinator shall ensure QA records are filed (arranged) by item or activity to ensure retrievability. Note: See Exhibit 3 – EMCBC QA Records Indexing Log
Step 10	The QA Records Coordinator shall store, maintain, protect, and ensure proper access controls for QA records at a predetermined location using either the Single or Dual Storage Method defined in Attachment 1.
REPLACEMENT OF QA RECORDS	
Step 11	The QA Records Coordinator shall notify the Records Management staff in the event QA records are lost or damaged.
Step 12	The QA Records Coordinator shall work with the Records Management staff to replace, restore, or substitute a lost or damaged QA record by obtaining a copy, if available, from the personnel who generated the QA record.
Step 13	If replacement or restoration is not practical, then the QA Records Coordinator shall document the loss and process as a noncompliance in accordance with the Quality Assurance and Oversight procedure, <i>Corrective Action</i> .
FINAL DISPOSITION OF QA RECORDS	
Step 14	The QA Records Coordinator shall transfer QA records to the Records Management staff when the identified QA record retention period has been met. This shall be in accordance with the Records Management procedure, <i>Transferring Inactive Paper Records to Records Holding Area/Records Storage Facility</i> .

3.0 References – Forms/Attachments/Exhibits

3.1 References

- SAP-OTSAM-414B-01, EMCBC Corrective Action
- SAP-OTSAM-243-05, Transferring Inactive Paper Records to Records Holding Area/Records Storage Facility

3.2 Forms

- FM-OTSAM-414E-01-F1, QA Records Transmittal Form

3.3 Attachments

- Attachment 1 – Storage of Quality Assurance Records

3.4 Exhibits

- Exhibit 1 – EMCBC QA Records Identification Matrix
- Exhibit 2 – EMCBC QA Records Classification Matrix
- Exhibit 3 – EMCBC QA Records Indexing Log

4.0 Records Generated

Records generated through implementation of this procedure are identified as follows and are maintained by the Office of Technical Support and Asset Management (OTSAM) or applicable site organization in accordance with the Organizational/Site File Plan:

Records Category Code	Records Title	Responsible Organization	QA Classification (Lifetime or Non-Permanent)
ADM 18.35.b	QA Records Identification Matrix QA Records Classification Matrix	OTSAM	Non-Permanent
ADM 18.36	QA Records Transmittal Form QA Records Indexing Log	OTSAM	Non-Permanent

EMCBC RECORD OF REVISION

DOCUMENT TITLE: Quality Assurance Records

If there are changes to the controlled document before the two-year review cycle, the revision number stays the same; one of the following will indicate the change:

I Placing a vertical black line in the left margin adjacent to sentence or paragraph that was revised; or

I Placing the words GENERAL REVISION at the beginning of the text. This statement is used when entire sections of the document are revised.

If changes and updates occur at the two-year review cycle, the revision number increases by one.

Rev. No.	Description of Changes	Revision on Pages	Date
0	Initial Document		08/24/12
1	Revised to the new MS Format, identified a QA records coordinator, added a records transmittal form, added a records indexing log, and authorized the single or dual storage method.	All	04/09/15